K111017

Section 5

JUN - 6 2011

Traditional 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 .92.

Applicant's Name and Address

Ultradent Products Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Diane Rogers
Title:	Regulatory Affairs Manager
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Date Summary Prepared:	May 31, 2011

Name of the Device

Trade Name:	ClearTemp
Common Name:	Dental Cement
Device Classification:	II
Classification Product Code:	EMA

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate device is: TempBond Clear by Sybron Dental Specialties (K053565)

Description of Device: ClearTemp is a light curable, temporary cement used specifically for luting thin translucent veneers on teeth.

Intended Use of the Device: ClearTemp is a provisional cement used for luting of thin translucent veneer restorations.

The following table shows that each of these devices are similar as test results comparing these devices show similar results. The devices are so equivalent that both of these companies follow standards that

show us how to test this type of a device and in Section 18 "Performance and Bench", you will see that test results show the devices have the same technological characteristics.

Function	ClearTemp	TempBond Clear (K6053565)
Flexural Strength	X	X
Hardness	X	X
Compressives	X	X
Cure Time	X	X
Depth of Cure	X	X
Sorption Solution	X	X
Radiopacity	X	X
Ambient Light Sensitivity	X	X
Film Thickness	X	X

Similarities in the Indications for Use:

ClearTemp		EMA	Provisional cement used for luting of thin translucent veneer restorations.
TempBond Clear	K053565	EMA	TempBond Clear with Triclosan is a dual cured, temporary, eugenol free, transparent, resin based cement with triclosan designed to be used in conjunction with temporary restorations such as crowns, bridges, inlays, onlays and splints.

Brief Description of Testing Performed

The following bench tests were conducted during the R & D phase on ClearTemp and compared to Sybron Dental Specialties TempBond Clear (K053565)

a. **Flexural Strength** – This test will show the strength of the bond during stress. A higher number than our competitors is good. The modulus side of this test shows the strength at which flexing the bond occurs. We prefer the product to be comparable to most of our competitors.
b. **Hardness** – This test shows the hardness of the bond. We prefer to stay within our competitors range.
c. **Compressives** – This test shows different forces on the resin. High numbers according to our competitors is acceptable.
d. **Depth of Cure** – This test shows how far a curing light penetrates into the cure. We want to stay at the high end of our competitors.
e. **Ambient Light Sensitivity** – This test shows the tie that the product will cure in ambient light. It shows working time with the product and cure time of the product. We want low times in this category.
f. **Sorption** – This test shows how much water the resin absorbs. We want low readings on this test.
g. **Film thickness** – testing bond strength at a defined thickness.
h. **Radiopacity** – verifying how clear the product shows up during an Xray.
i. **Sorption Soluability**- testing whether the product degrades in solutions or saliva

Clinical Summary

A complete Clinical Summary of ClearTemp is included in Section 20. We conducted a literature study to show safety and effectiveness of ClearTemp. ClearTemp is a provisional cement used for luting of thin translucent veneer restorations. The product can be used on any age patient when they have had veneers professionally installed. The device has the same technological characteristics compared to Sybron Dental Specialities TempBond Clear. These materials have been widely used by numerous manufacturers in the dental industry.

The efficacy or suitability to the intended purpose of ClearTemp has been demonstrated by a combination of in-house testing and side-by-side comparisons to predicate devices currently on the market. Results of our bench testing indicates that ClearTemp performs as well or better than the predicate device currently on the market.

Summary
Risk/Benefit Review

Considering the safe history of our predicate, TempBond Clear by Sybron Dental Specialities (K053565) ClearTemp is considered a safe medical device. Our research indicates that our predicate has been used by many dentists and large group practices in the United States and purchased by a large

number of international distributors. To date, there have been no reported complaints of local or systemic adverse effects associated with the use of these products.

ClearTemp was tested for biocompatibility in Cytotoxicity, Sensitization, Irritation and Genotoxicity tests according to ISO 10993-1:2009. An abstract of the testing along with signed test reports are included in Section 15 "Biocompatibility" of this submission.

In conclusion, ClearTemp has been designed and manufactured with the intended use and claims for the product in mind. Scientific literature, etc. has been collected and evaluated to determine safety and efficacy of similar products used for the same indication. Following the clinical review as documented above, Ultradent Products, Inc. deems that when this device is used under the conditions and for the purposes intended, it will not compromise the clinical condition or the safety of the patient and the association with its use constitutes acceptable risks when weighed against the benefits to the patient. Therefore, the product is compatible with a high level of protection of health and safety and may be released to the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Diane Rogers
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505 West 10200 South
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JUN - 6 2011

Re: K111017
Trade/Device Name: ClearTemp
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: April 1, 2011
Received: April 12, 2011

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K111017

Device Name: ClearTemp

Indications for Use:

ClearTemp is a provisional cement used for luting of thin translucent veneer restorations.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111017

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(Posted November 13, 2003)